
चिकित्सीय वस्त्रादि — फोम मरहम पट्टी—
विशिष्टि

Medical Textiles — Foam Dressing —
Specification

ICS 11.140; 59.080.01

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FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards, after the draft finalized by Technical Textiles for Medtech Applications Sectional Committee had been approved by the Textile Division Council.

The composition of the Committee responsible for the formulation of this standard is given in Annex D.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated, expressing the result of a test or analysis shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

MEDICAL TEXTILES — FOAM DRESSING — SPECIFICATION

1 SCOPE

1.1 This standard specifies the requirements for foam dressing intended for medical use.

1.2 This standard does not cover the drug component applied/coated on the product.

2 REFERENCES

The standards listed in Annex A contain provisions, which through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated in Annex A.

3 TERMS AND DEFINITIONS

For the purpose of this standard, the following definitions shall apply:

3.1 Biocompatibility — The ability to be in contact with a living system without producing an adverse effect.

3.2 Foam Dressing — A sterile or non-sterile dressing containing foam to absorb the wound exudates in combination with an adhesive flexible film with barrier to water and other outside contaminants.

3.3 Manufacturer — Natural or legal person with responsibility for the processing of raw material or inputs in any manner that results in the emergence of a new product having a distinct name, character and use.

4 MANUFACTURE

4.1 The foam dressing shall be made from suitable material that is not prohibited for use for the purpose under any applicable law /regulation in force so that the product made out of this meets the requirements specified in this standard.

4.2 The manufacturer shall establish a formal quality management system including requirements for the product development, design, production, testing, packaging, labeling, distribution and provision of related services as per Medical device rules, 2017 for foam dressing. The quality management system shall

include a risk management procedure where inputs for product realization shall include the outputs from risk management.

4.3 Microbiological monitoring (as per ISO 14698-1), air monitoring of clean room (as per ISO 14644-1), sterilization (as per IS/ISO 11135), packaging (as per IS/ISO 11607-1 and 2), validation (as per IS/ISO 11137-1 and 2, ISO 11138-7) and residual sterility (IS/ISO 10993-7) shall be maintained by the manufacture.

5 REQUIREMENTS

5.1 A manufacturing and processing specification shall be designed and validated for the product, including visual and hygienic cleanliness. The validation shall include all steps involved in manufacturing and processing.

5.2 The key manufacturing and processing variables shall be identified, monitored and recorded. The type and frequency of routine monitoring shall be documented.

5.3 During manufacturing and processing, the control of decontamination, disinfection procedures and the traceability of sterilization shall be maintained.

5.4 The foam dressing shall conform to the requirements specified in Table 1.

6 PACKAGING AND STERILIZATION

6.1 For packaging of the products, requirements as per IS/ISO 11607-1 and 2 shall be followed.

For packaging and sterilization, the Medical Device Rule 2017 shall be followed.

6.2 Validation of sterilization process shall be done as per IS/ISO 11135, IS/ISO 11137-1 and 2, ISO 11138-7 and, IS/ISO 10993-7 standards.

7 MARKING

7.1 Each pack of the dressings shall be legibly and indelibly marked with following information:

- a) Name of the product;
- b) Dimension /size of the product;
- c) Manufacturer's name, initials or trademark, if any;

Table 1 Performance Requirements for Foam Dressing
(Clause 5.4)

Sl No. (1)	Characteristic (2)	Requirement (3)	Method of Test, Ref to (4)
i)	Water vapour permeability, g/m ² /24 h, <i>Min</i>	500	IS 14944
ii)	Waterproofness	Complies with test	IS 14944
iii)	Absorbency	Complies with test	Annex B
iv)	pH	6.0 - 8.0	IS 1390
v)	Water soluble substances percent, <i>Max</i> 1	IS 14944	
vi)	Extractable tin	not more than 6 ppm tin (Sn)	Annex C
vii)	Biocompatibility evaluation**		
	a) Cytotoxicity	None	IS/ISO 10993-5
	b) Irritation and skin sensitization	Non-irritant and non-sensitizer	IS/ISO 10993-10

** Remarks: Confirm the biocompatibility of raw material at designed stage. The biocompatibility evaluation shall be carried out once for existing raw material and whenever there is a change in the raw material or source of supply for manufacturing the product.

- d) Month and year of manufacture, batch /lot number;
- e) Labelling and marking requirements shall be followed as per Medical Device Rules 2017; and
- f) Any other statutory requirement as required by the law in force.

7.2 BIS Certification Marking

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act, 2016* and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

8 SAMPLING AND CRITERIA FOR CONFORMITY

8.1 Lot

All the foam dressings of the same material and dimensions produced under similar conditions of manufacture shall constitute a lot.

8.1.1 Each lot shall be tested separately for ascertaining the conformity of the lot.

8.1.2 The number of foam dressings to be selected from the lot shall depend on the size of the lot and shall be in accordance with column 2 and 3 of Table 2.

8.1.3 These dressings shall be selected at random from the lot. For this purpose, reference may be made to IS 4905.

8.2 Number of Tests and Criteria for Conformity

8.2.1 All the dressings selected as per column 3 of Table 2 shall be examined for workmanship and finish (see 5.1).

8.2.1.1 Any dressing failing in one or more of the above requirements shall be termed as defective. The lot shall be considered as conforming to the above requirements, if the total number of defectives found in the sample is less than or equal to the acceptance number given in column 4 of Table 2. Otherwise, the lot shall be rejected.

Table 2 Number of Foam Dressings Compressed to be Selected

(Clauses 8.1.2, 8.2.1 and 8.2.1.1)

Sl No. (1)	Lot Size (2)	Destructive Testing	
		No. of Dressings to be Selected (3)	Acceptance Number (4)
i)	Up to 280	8	0
ii)	281 to 500	8	0
iii)	501 to 1 200	13	0
iv)	1 201 to 3 200	13	0
v)	3 201 and above	20	1

ANNEX A

(Clause 2)

LIST OF REFERRED INDIAN STANDARDS

<i>IS/Other Publication</i>	<i>Title</i>	<i>IS/Other Publication</i>	<i>Title</i>
1390 : 2019	Textiles — Determination of pH of aqueous extracts (<i>second revision</i>)	IS/ISO 11137-1 : 2006	Sterilization of health care products — Radiation: Part 1 Requirements for development, validation and routine control of a sterilization process for medical devices
4905 : 2015	Random sampling and randomization procedures (<i>first revision</i>)		
14944 : 2001	Surgical dressings — Methods of test	IS/ISO 11137-2 : 2013	Sterilization of health care products — Radiation: Part 2 Establishing the sterilization dose
IS/ISO 10993-5 : 2009	Biological evaluation of medical devices: Part 5 Tests for in vitro cytotoxicity	IS/ISO 11135 : 2014	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices
IS/ISO 10993-7 : 2008	Biological evaluation of medical devices: Part 7 Ethylene oxide sterilization residuals		
IS/ISO 10993-10 : 2010	Biological evaluation of medical devices: Part 10 Tests for irritation and skin sensitization	ISO 11138-7 : 2019	Sterilization of health care products — Biological indicators — Part 7: Guidance for the selection, use and interpretation of results
IS/ISO 11607-1 : 2006	Packaging for terminally sterilized medical devices: Part 1 Requirements for materials, sterile barrier systems and packaging systems	ISO 14644-1 : 2015	Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration
IS/ISO 11607-2 : 2006	Packaging for terminally sterilized medical devices: Part 2 Validation requirements for forming, sealing and assembly processes	ISO 14698-1 : 2003	Cleanrooms and associated controlled environments — Biocontamination control — Part 1: General principles and Methods

ANNEX B

[Clause 5.4, Table 1, Sl No. (iii)]

TEST METHODS FOR ABSORBENCY

Weigh a sample of dimension 5 cm x 5 cm and immerse in simulated exudates for 1 h. A weight may be attached below the sample to ensure that it remains wholly immersed during this period. Remove the sample, allow to drain freely without compression at an angle of 45° for 5 min and reweigh. The increase in weight is not less than 7.5 times the initial weight. The exudates preparation procedure is as follows.

The test solution is constituted of an ionic composition in order to replicate wound exudates or human serum.

The ionic composition basically composition by sodium chloride and calcium chloride that consists of 142 mmol of sodium ions and 2.5 mmol of calcium ions as the chloride salts. It is prepared in 1 litre volumetric flask by dissolving 8.298 g of sodium chloride and 0.368 g of calcium chloride dehydrate in distilled water and making into it 1 litre. The test solution is warmed into $37 \pm 1^\circ\text{C}$. The prepared sample is immersed into it. It has to kept in oven at $37 \pm 1^\circ\text{C}$ for 15/30 min more.

ANNEX C

[Clause 5.4, Table 1, Sl No. (vi)]

TEST METHODS FOR EXTRACTABLE TIN

To 5 g, previously cut into pieces not more than 50 mg in weight, add 50 ml of a 0.9 percent w/v solution of sodium chloride and shake for 4 h. Filter and determine

by atomic absorption spectrophotometry, measuring at 224.6 nm and using a nitrous oxide-acetylene flame.

ANNEX D*(Foreword)***COMMITTEE COMPOSITION**

Technical Textiles for Medtech Applications, TXD 36

<i>Organization</i>	<i>Representative(s)</i>
The South India Textile Research Association, Coimbatore	DR PRAKASH VASUDEVAN (Chairman)
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All Indian Institute of Medical Sciences, New Delhi	DR VIJAYDEEP SIDDHARTH DR ANOOP DAGA (<i>Alternate</i>)
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The Synthetics & Art Silk Mills Research Association, Mumbai	DR MANISHA MATHUR SHRI RAVI SINGH (<i>Alternate</i>)
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This Indian Standard has been developed from Doc No.: TXD 36 (14824).

Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

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Published by BIS, New Delhi